

Pharmanex, Ir 625 Cochran Stri Simi Valley, Califori 93065-193 805.582.930 Fax 805.582.930

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BY FEDERAL EXPRESS

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C. St. S.W. Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Black Cohosh**, containing standardized extract of Black Cohosh, with the following labeling statements:

- 1. Natural menopausal support.
- 2. Helps ease discomfort.
- 3. Promotes hormonal balance.
- 4. The naturally-occurring compounds in Pharmanex Black Cohosh formula can help ease the physical and emotional changes associated with menopause, normalize menstrual cycles, and promote hormonal balance.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely.

Michael Chang

Sr. V.P. Research & Development

also see docket 975-0163

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